

REMARKS

Claims 1-28 were pending in the application. Claims 13-19 and 23-28 have been cancelled, without prejudice, as being directed to a non-elected invention. Claim 5 has been amended. Applicants reserve the right to prosecute the same or similar claims in the instant or in a subsequent patent application. Accordingly, claims 1-12 and 20-22 are currently pending. For the Examiner's convenience all of the pending claims are set forth in Appendix B.

Support for the amendments to claim 5 can be found throughout the specification and claims as originally filed. In particular, support for the amendments to claim 5 may be found at page 2, lines 3-7; at page 2, lines 19-24; at page 2, lines 31-33; at page 12, lines 1-16; and at page 3, lines 8-10 of the specification.

Attached hereto is a marked-up version of the changes made to claim 5 by the current amendments. Appendix A is captioned "Version with Markings to Show Changes Made."

No new matter has been added. Any amendments to and/or cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done solely to expedite the prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Election/Restrictions

Applicants gratefully acknowledge the Examiner's indication that claims 1 and 2 are allowable.

Priority

Applicants acknowledge the Examiner's indication that the claim of priority for the instant application is to U.S. provisional application Serial Number 60/170,182, filed on December 10, 1999. However, Applicants further submit that the instant application also claims priority to U.S. Serial No. 09/733,818 filed on December 8, 2000, as set forth at page 1, lines 4-7 of the originally filed specification.

Drawings

Applicants respectfully submit that the formal drawings enclosed herewith are in compliance with the changes requested on PTO Form 948 and with 37 C.F.R. 1.85(a).

Objection to the Specification

The Examiner has objected to the specification and has requested appropriate correction, because "the specification makes references to ATCC accession number throughout the disclosure (for example on page 2), but fails to provide the accession number of the deposit."

Applicants respectfully submit that, pursuant to *In re Lundak*, Applicants have the right to make a deposit of a plasmid containing a nucleic sequence encoding bcap73 prior to the issuance of the application. *In re Lundak* 723 F2d. 1216, 227 USPQ 90 (Fed. Cir. 1985). Accordingly, Applicants submit that consideration will be given to whether the specification will be amended to include the ATCC deposit information for the bcap73 molecule when this information becomes available, and prior to issuance of the application, if appropriate.

Rejection of Claims Under 35 U.S.C. §112, First Paragraph

Rejection of Claim 3 Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claim 3 under 35 U.S.C. § 112, first paragraph for lacking a sufficient written description for enablement based on the deposit requirement.

As set forth above, Applicants respectfully submit that, pursuant to *In re Lundak*, Applicants have the right to make a deposit of a plasmid containing a nucleic sequence encoding bcap73 prior to the issuance of the application. *In re Lundak* 723 F2d. 1216, 227 USPQ 90 (Fed. Cir. 1985). Accordingly, Applicants submit that consideration will be given to whether the specification will be amended to include the ATCC deposit information for the bcap73 molecule when this information becomes available, and prior to issuance of the application, if appropriate.

Rejection of Claims 4-12, 20-22 Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 4-12 and 20-22 under 35 U.S.C. § 112, first paragraph as containing "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." The Examiner is of the opinion that

[w]hile the specification provides adequate written description for the claimed invention (methods and products) only with regard to the SEQ ID NO:1 and/or SEQ ID NO:3 and the polypeptide encoded comprising the amino acid sequence set forth in SEQ ID NO:2 of beta CAP73, the specification fails to describe the other species within the genus of 'nucleic acids that encode naturally occurring allelic variants of a polypeptide' or 'nucleic acid molecules at least 60% identical to the nucleotide sequences of SEQ ID NO:1 or 3, or a fragment thereof'. Further, the specification fails to describe the other species within the genus of 'nucleic acid molecules encoding a polypeptide comprising an amino acid sequence at least about 50% identical to the amino acid sequence of SEQ ID NO:2' (page 5 of Office Action dated July 31, 2002).

Claim 4

Applicants respectfully traverse the aforementioned rejection and respectfully submit that the instant specification does teach identifying structural characteristics or properties of the claimed molecules. Regarding claim 4, drawn to naturally occurring allelic variants of a polypeptide comprising the amino acid sequence set forth in SEQ ID NO:2, Applicants respectfully submit that there is sufficient written description in Applicants' specification regarding naturally occurring allelic variants to inform a skilled artisan that Applicants were in possession of the claimed invention at the time the application was filed, as required by section 112, first paragraph (see M.P.E.P. 2163.02). The sufficiency of a disclosure in meeting the written description requirement of 35 U.S.C. §112 for claims to a genus of cDNAs was addressed in the Eli Lilly case in which the Court stated that

[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus *or a recitation of*

structural features common to the members of the genus, which features constitute a substantial portion of the genus [emphasis added].

The Regents of the University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Therefore, as articulated by the Federal Circuit, a claim to a genus of chemical compounds satisfies the written description requirement when its accompanying specification either defines by sequence a representative number of its members falling within the scope of the genus or ***when its accompanying specification defines the structural features common to a substantial portion of the genus.*** The instant specification satisfies this requirement for the claimed invention because the claimed genus of naturally occurring allelic variants of the present invention is defined by structural features that are described in the specification, recited in the claims, and commonly possessed by its members. To begin with, the specification teaches the structure of the bcap73 polypeptides, *i.e.*, the amino acid sequence of the bcap73 polypeptides (SEQ ID NO:2) as well as the structure of the bcap73 nucleic acid molecules, *i.e.*, the nucleotide sequence of the nucleic acid molecules encoding these bcap73 polypeptides (SEQ ID NOS:1 and 3). The originally filed specification further teaches at, for example, page 16, lines 30-33, that “*functional* allelic variants will typically contain only conservative substitution of one or more amino acids of SEQ ID NO:2, or substitution, deletion or insertion of non-critical residues in non-critical regions of the protein.” In addition, Applicants teach multiple binding domains, such as the erzin binding domain, the ankyrin binding domain, and the actin binding domain, that may be included in the polypeptides of the present invention (see page 3, lines 30-36 of the specification). In particular, Applicants teach that sequence conservation among bcap73-related family members indicates that these proteins are likely to include at least one ankyrin domain (see page 10, lines 3-4 of the specification). The specification further discloses “[b]ovine bcap73 has... a signature pattern at about amino acid residues 55 to 85, 88 to 118, 121 to 151, 184 to 214, 217 to 247, and 250 to 280 of SEQ ID NO:2” (see page 10, lines 16-18 of the specification).

In summary, Applicants have described a genus of naturally occurring allelic variants based on structural features that are common to a substantial portion of the genus and have provided within the instant specification the amino acid sequence of members

of this genus that possess these features. Thus, the instant specification satisfies the written description requirement for the claimed invention, using the standard set forth by the Federal Circuit in The Regents of the University of California.

In view of the foregoing, Applicants respectfully submit that one of skill in the art can readily envision polypeptides comprising the polypeptide sequences of SEQ ID NO:2, as well as naturally occurring allelic variants of the bcap73 polypeptides of the present invention. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the foregoing section 112, first paragraph rejection.

Claim 5

Regarding claim 5(a) and (c), and the claims depending therefrom, Applicants respectfully traverse the foregoing rejection. Example 14 of the *Revised Interim Written Description Guidelines Training Materials* provides that a claim directed to variants of a protein having SEQ ID NO:3 "that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction of A→B" with an accompanying specification that discloses a single species falling within the claimed genus, satisfies the requirements of 35 U.S.C. §112, first paragraph for written description. The rationale behind the foregoing conclusion, as presented by the *Written Description Guidelines*, is that "[t]he single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which Applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO:3 which are capable of the specified catalytic activity." The Guidelines also provide that "***[t]he procedures for making variants of SEQ ID NO:3 are conventional in the art and an assay is described which will identify other proteins having the claimed catalytic activity. Moreover, procedures for making variants of SEQ ID NO:3 which have 95% identity to SEQ ID NO:3 and retain its activity are conventional in the art.***"

Similarly, in the present case, claim 5(a) is directed to a nucleic acid molecule comprising a nucleotide sequence which is at least 85% identical to the entire nucleotide sequence of SEQ ID NO:1 or 3, wherein said nucleic acid molecule encodes a protein having a bcap73 activity, or a complement thereof. Applicants have disclosed in the instant specification assays for identifying all of the at least 85% identical variants of

SEQ ID NO:1 or 3. Moreover, Applicants have disclosed in the specification assays that may be used to test whether these variants have a bcap73 activity (see page 2, lines 31-33 and at page 12, lines 1-16 of the specification). Likewise, claim 5(c) is directed to a nucleic acid molecule comprising a nucleotide sequence which is at least 55% identical to the entire nucleotide sequence of SEQ ID NO:2, wherein said nucleic acid molecule encodes a protein having a bcap73 activity, or a complement thereof. Applicants have disclosed in the instant specification assays for identifying all of the at least 55% identical variants of SEQ ID NO:1 or 3.

Thus, based on the teachings in Applicants' specification, one of skill in the art would conclude that Applicants were in possession of the claimed invention at the time of filing. Moreover, as indicated by the Guidelines, "procedures for making variants of SEQ ID NO:3 which have 95% identity to SEQ ID NO:3 and retain its activity are conventional in the art." Thus, based on the teachings in Applicants' specification and the knowledge generally available in the art at the time of the invention, the skilled artisan would be able to make and use the claimed invention using only routine experimentation.

With regard to claim 5(b), directed to nucleic acid molecules comprising a fragment of at least 107 contiguous nucleotides of a nucleic acid comprising the nucleotide sequence of SEQ ID NO:1 or 3; claim 5(d), directed to nucleic acid molecules comprising a fragment of a polypeptide comprising the amino acid sequence of SEQ ID NO:2, wherein the fragment comprises at least 20 contiguous amino acid residues of the amino acid sequence of SEQ ID NO:2; and the claims depending therefrom, Applicants traverse the foregoing rejections for the following reasons.

In Example 15 of the *Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. §112, First Paragraph Written Description Requirement* the "theoretical specification" discloses a messenger RNA sequence, SEQ ID NO:1, which encodes a human growth hormone. The "theoretical specification" claims antisense molecules that inhibit the production of human growth hormone. The Guidelines provide that

[c]onsidering the specification's disclosure of (1) *the sequence (SEQ ID NO:1) which defines and limits the structure of any effective molecules such that one skilled in the art would be able to immediately envisage*

members of the genus embraced by the claim and 2) the functional characteristics of the claimed invention as well as a routine art-recognized method of screening for antisense molecules which provide further distinguishing characteristics of the claimed invention, along with, 3) the general level of knowledge and skill in the art, one skilled in the art would conclude that applicant was in possession of the invention.....***the claimed invention is adequately described. (Emphasis added).***

Similar to Example 15 of the *Interim Guidelines*, the instant specification describes the nucleotide sequence of the nucleic acid molecules of the invention (SEQ ID NOS:1 and 3) and the amino acid sequence of the polypeptides of the invention (SEQ ID NO:2) ***which define and limit the structure of any nucleic acid or polypeptide fragments such that one skilled in the art would be able to immediately envisage members of the genus embraced by the polypeptide fragment claims.*** In addition, Applicants teach multiple binding domains, such as the erzin binding domain, the ankyrin binding domain, and the actin binding domain, that may be included in the polypeptides of the present invention (see page 3, lines 30-36 of the specification).

Furthermore, as provided in Example 15 of the *Interim Guidelines*, the generation of nucleic acid fragments is *routine*. For example, (as indicated in Example 15 of the *Interim Guidelines*) any specified fragment can be ordered from a commercial synthesizing service. Based on the foregoing, it is evident that Applicants were in possession of the claimed invention at the time of filing. Moreover, it is evident that following the teachings in Applicants' specification and the knowledge generally available in the art at the time of the invention, the skilled artisan would be able to make and use the claimed invention using only routine experimentation.

In view of all of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of the pending claims under 35 U.S.C. § 112, first paragraph.

Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 3, 6-12, and 20-22 under 35 U.S.C. § 112, second paragraph as being "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."

Applicants respectfully traverse the foregoing rejection.

Claim 3

The Examiner advises Applicants to provide the accession number of the deposit. Applicants respectfully submit that, pursuant to *In re Lundak*, Applicants have the right to make a deposit of a plasmid containing a nucleic sequence encoding bcap73 prior to the issuance of the application. *In re Lundak* 723 F2d. 1216, 227 USPQ 90 (Fed. Cir. 1985). Accordingly, Applicants submit that consideration will be given to whether the specification will be amended to include the ATCC deposit information for the bcap73 molecule when this information becomes available, and prior to issuance of the application, if appropriate.

Claim 22

The Examiner is of the opinion that the term "compound which selectively hybridizes to a nucleic acid" is "confusing in its use of the broad term compound."

Applicants respectfully traverse and submit that the instant specification teaches the use of a kit, wherein the kit comprises a labeled compound or agent capable of detecting bcap73 in the sample (see page 59, lines 21-27 of the specification). It is well-known in the art that compounds, for example, antisense molecules and probes, can selectively hybridize to nucleic acid molecules. Moreover, one of skill in the art at the time of invention would know that molecules that can selectively hybridize to a nucleic acid molecule, such as the nucleic acid molecules of any one of claims 1, 2, 3, 4, or 5, are encompassed by the term "compound." Thus, Applicants respectfully request reconsideration and withdrawal of the foregoing rejection.

Claims Rejected Under 35 U.S.C. § 102

Rejection of Claims 5-11 Under 35 U.C.S. § 102(b) as being Anticipated by Wilkin *et al.*

The Examiner has rejected claims 5-11 under 35 U.S.C. § 102 (b) as being anticipated by Wilkin *et al.* (1996, J. Biol. Chem. Vol. 271, No. 44, pp. 28451-28457). Applicants respectfully traverse and request reconsideration. Applicants respectfully submit that the pending claims are not anticipated by Wilkin *et al.* because the sequence

taught by Wilkin *et al.* does not encode a fragment which is at least 85% identical to the nucleotide sequence of SEQ ID NO:1 or 3.

As the Examiner is aware, 35 U.S.C. § 102 requires that in order to anticipate the claimed invention, the prior art reference must teach *each and every element* of the claimed invention. Here, the Wilkin *et al.* clone cited by the Examiner is only 83% homologous (not 85% homologous as required by claim 5(a), as amended herein) to SEQ ID NO:1. Thus, Applicants further submit that the rejection no longer applies to claim 5 as amended herein. Applicants therefore respectfully request reconsideration and withdrawal of the rejection.

Rejection of Claims 5-12 Under 35 U.C.S. § 102(b) as being Anticipated by Jacobs *et al.*

The Examiner has rejected claims 5-12 under 35 U.S.C. § 102 (b) as being anticipated by Jacobs *et al.* (1998, PCT International Publication, WO 98/49302). Applicants respectfully traverse and request reconsideration. Applicants respectfully submit that the pending claims are not anticipated by Jacobs *et al.* because the sequence taught by Jacobs *et al.* does not encode a fragment which is at least 55% identical to the nucleotide sequence of SEQ ID NO:2.

As the Examiner is aware, 35 U.S.C. § 102 requires that in order to anticipate the claimed invention, the prior art reference must teach *each and every element* of the claimed invention. Here, the Jacobs *et al.* sequence cited by the Examiner is only 50% homologous (not 55% homologous as required by claim 5(c), as amended herein) to SEQ ID NO:2. Thus, Applicants further submit that the rejection no longer applies to claim 5 as amended herein. Applicants therefore respectfully request reconsideration and withdrawal of the rejection.

Rejection of Claims 5-11 Under 35 U.C.S. § 102(b) as being Anticipated by Linskens *et al.*

The Examiner has rejected claims 5-11 under 35 U.S.C. § 102 (b) as being anticipated by Linskens *et al.* (1998, U.S. Patent No. 5,744,300). Applicants respectfully traverse and request reconsideration. Applicants respectfully submit that the pending claims are not anticipated by Linskens *et al.* because the sequence taught by Linskens *et*

al. (SEQ ID NO:38) does not encode a fragment which is at least 20 contiguous amino acid residues of SEQ ID NO:2.

As the Examiner is aware, 35 U.S.C. § 102 requires that in order to anticipate the claimed invention, the prior art reference must teach *each and every element* of the claimed invention. Here, the Linskens *et al.* sequence cited by the Examiner (SEQ ID NO:38) encodes a fragment of a polypeptide that has contiguous homology over 19 amino acid residues (not 20 contiguous amino acid residues as required by claim 5(d), as amended herein) to SEQ ID NO:2. Thus, Applicants further submit that the rejection no longer applies to claim 5 as amended herein. Applicants therefore respectfully request reconsideration and withdrawal of the rejection.

Rejection of Claim 22 Under 35 U.C.S. § 102(b) as being Anticipated by Wilkin *et al.*

The Examiner has rejected claim 22 under 35 U.S.C. § 102 (b) as being anticipated by Wilkin *et al.* (1996, J. Biol. Chem. Vol. 271, No. 44, pp. 28451-28457). Applicants respectfully traverse and request reconsideration. Applicants respectfully submit that the pending claims are not anticipated by Wilkin *et al.* because the sequence taught by Wilkin *et al.* does not encode a fragment which is at least 85% identical to the nucleotide sequence of SEQ ID NO:1 or 3.

As the Examiner is aware, 35 U.S.C. § 102 requires that in order to anticipate the claimed invention, the prior art reference must teach *each and every element* of the claimed invention. Here, the Wilkin *et al.* clone cited by the Examiner is only 83% homologous (not 85% identical as required by claim 5(a), as amended herein) to SEQ ID NO:1. Thus, Applicants further submit that the rejection no longer applies to claim 22, as claim 5, from which claim 22 depends, has been amended herein. Applicants therefore respectfully request reconsideration and withdrawal of the rejection.

Rejection of Claims 20 and 21 Under 35 U.C.S. § 102(b) as being Anticipated by Wilkin *et al.*

The Examiner has rejected claims 20 and 21 under 35 U.S.C. § 102 (b) as being anticipated by Wilkin *et al.* (1996, J. Biol. Chem. Vol. 271, No. 44, pp. 28451-28457). Applicants respectfully traverse and request reconsideration. Applicants respectfully submit that the pending claims are not anticipated by Wilkin *et al.* because the sequence

taught by Wilkin *et al.* does not encode a fragment which is at least 85% identical to the nucleotide sequence of SEQ ID NO:1 or 3.

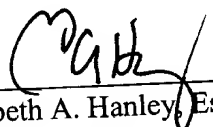
As the Examiner is aware, 35 U.S.C. § 102 requires that in order to anticipate the claimed invention, the prior art reference must teach *each and every element* of the claimed invention. Here, the Wilkin *et al.* clone cited by the Examiner is only 83% homologous (not 85% identical as required by claim 5(a), as amended herein) to SEQ ID NO:1. Thus, Applicants further submit that the rejection no longer applies to claims 20 and 21, as claim 5, from which claims 20 and 21 depend, has been amended herein. Applicants therefore respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicants' Attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400.

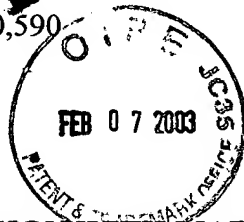
Respectfully submitted,

LAHIVE & COCKFIELD, LLP


Elizabeth A. Hanley, Esq.
Reg. No. 33,505
Attorney for Applicants

28 State Street
Boston, MA 02109
Tel. (617) 227-7400

Date: **January 30, 2003**

APPENDIX AVERSION WITH MARKINGS TO SHOW CHANGES MADE

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Please cancel claims 13-19 and 23-28, without prejudice, as being directed to a non-elected invention.

Please amend claim 5 as follows:

5. (Amended) An isolated nucleic acid molecule selected from the group consisting of:

a) a nucleic acid molecule comprising a nucleotide sequence which is at least [60] 85% identical to the nucleotide sequence of SEQ ID NO: 1 or 3, or a complement thereof, wherein said nucleic acid molecule encodes a protein having bcap73 activity, or a complement thereof;

b) a nucleic acid molecule comprising a fragment of at least 107 nucleotides of a nucleic acid comprising the nucleotide sequence of SEQ ID NO: 1 or 3, or a complement thereof;

c) a nucleic acid molecule which encodes a polypeptide comprising an amino acid sequence at least about [50] 55% identical to the amino acid sequence of SEQ ID NO: 2, wherein said nucleic acid molecule encodes a protein having bcap73 activity, or a complement thereof; and

d) a nucleic acid molecule which encodes a fragment of a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, wherein the fragment comprises at least [15] 20 contiguous amino acid residues of the amino acid sequence of SEQ ID NO: 2.

APPENDIX B**PENDING CLAIMS**

1. An isolated nucleic acid molecule selected from the group consisting of:
 - (a) a nucleic acid molecule comprising the nucleotide sequence set forth in SEQ ID NO: 1; and
 - (b) a nucleic acid molecule comprising the nucleotide sequence set forth in SEQ ID NO: 3.
2. An isolated nucleic acid molecule which encodes a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 2.
3. An isolated nucleic acid molecule comprising the nucleotide sequence contained in the plasmid deposited with ATCC® as Accession Number _____.
4. An isolated nucleic acid molecule which encodes a naturally occurring allelic variant of a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 2.
5. An isolated nucleic acid molecule selected from the group consisting of:
 - a) a nucleic acid molecule comprising a nucleotide sequence which is at least 85% identical to the nucleotide sequence of SEQ ID NO: 1 or 3, or a complement thereof, wherein said nucleic acid molecule encodes a protein having bcap73 activity, or a complement thereof;
 - b) a nucleic acid molecule comprising a fragment of at least 107 nucleotides of a nucleic acid comprising the nucleotide sequence of SEQ ID NO: 1 or 3, or a complement thereof;

c) a nucleic acid molecule which encodes a polypeptide comprising an amino acid sequence at least about 55% identical to the amino acid sequence of SEQ ID NO: 2, wherein said nucleic acid molecule encodes a protein having bcap73 activity, or a complement thereof; and

d) a nucleic acid molecule which encodes a fragment of a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, wherein the fragment comprises at least 20 contiguous amino acid residues of the amino acid sequence of SEQ ID NO: 2.

6. An isolated nucleic acid molecule which hybridizes to the nucleic acid molecule of any one of claims 1, 2, 3, 4, or 5 under stringent conditions.

7. An isolated nucleic acid molecule comprising a nucleotide sequence which is complementary to the nucleotide sequence of the nucleic acid molecule of any one of claims 1, 2, 3, 4, or 5.

8. An isolated nucleic acid molecule comprising the nucleic acid molecule of any one of claims 1, 2, 3, 4, or 5, and a nucleotide sequence encoding a heterologous polypeptide.

9. A vector comprising the nucleic acid molecule of any one of claims 1, 2, 3, 4, or 5.

10. The vector of claim 9, which is an expression vector.

11. A host cell transfected with the expression vector of claim 10.

12. A method of producing a polypeptide comprising culturing the host cell of claim 11 in an appropriate culture medium to, thereby, produce the polypeptide.

20. A method for detecting the presence of a nucleic acid molecule of any one of claims 1, 2, 3, 4, or 5 in a sample comprising:

- a) contacting the sample with a nucleic acid probe or primer which selectively hybridizes to the nucleic acid molecule; and
- b) determining whether the nucleic acid probe or primer binds to a nucleic acid molecule in the sample to thereby detect the presence of a nucleic acid molecule of any one of claims 1, 2, 3, 4, or 5 in the sample.

21. The method of claim 20, wherein the sample comprises mRNA molecules and is contacted with a nucleic acid probe.

22. A kit comprising a compound which selectively hybridizes to a nucleic acid molecule of any one of claims 1, 2, 3, 4, or 5 and instructions for use.